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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Yossi Gross et al
Serial No:	--
Filed:	Herewith
For:	MECHANICAL AND ELECTRICAL SENSING FOR INCONTINENCE TREATMENT DEVICE
Examiner:	--
Art Unit:	--

Commissioner For Patents
Washington, D.C. 20231

Sir:

PRELIMINARY AMENDMENT

In the Specification:

Before examining the above-referenced application, and prior to calculation of the filing fee, amend the specification by inserting before the first line the sentence:

This application is a continuation application of U.S. Patent Application no. 09/413,272 ("the parent application"), filed October 6, 1999, entitled INCONTINENCE TREATMENT DEVICE, now pending, which was a continuation-in-part of Patent Application serial no. 09/167,244, filed October 6, 1998, now abandoned.

In the Claims:

Kindly delete claims 3, 5-12, 15-24, 31-40, 42-57, 62, 63, and 65-89 without prejudice, as they were allowed in the parent application. Kindly add the following new claims:

92. (New) A device for inhibiting involuntary urine flow, comprising:

at least one electrode, which is adapted to be implanted in a pelvic muscle of a patient;

a sensor, which is adapted to sense a change in pressure of an abdomen or a urinary bladder of the patient and to generate a signal responsive thereto; and

a control unit, which is adapted to receive the signal, analyze the signal to determine a level of abdominal stress of the patient, and, responsive thereto, apply an electrical waveform to the electrode which stimulates the muscle to contract so as to inhibit involuntary urine flow through the patient's urethra due to the stress.

93. (New) A device according to claim 92, wherein the control unit is adapted to apply the electrical waveform responsive to electromyographic signals received from the at least one electrode.

94. (New) A device according to claim 92, wherein the control unit comprises a processor, which is adapted to analyze the signals so as to determine when an involuntary urine flow is likely, whereupon the waveform is applied.

95. (New) A device according to claim 94, wherein the processor is programmable to vary one or more parameters associated with the application of the waveform.

96. (New) A device according to claim 95, and comprising a wireless receiver, which is adapted to receive data for programming the processor from a programming unit outside the patient's body.

97. (New) A device according to claim 92, wherein the control unit is adapted to be implanted in the body of the patient.

98. (New) A device according to claim 97, wherein the control unit comprises a rechargeable power source.

99. (New) A device according to claim 98, wherein the power source is recharged by inductive energy transfer, substantially without electrical contact between the control unit and any object outside the patient's body.

100. (New) A device according to claim 92, wherein the at least one electrode is adapted to be implanted in the levator ani muscle.

101. (New) A device according to claim 92, wherein the at least one electrode is adapted to be implanted in the urethral sphincter muscle.

102. (New) A device according to claim 92, wherein the at least one electrode is adapted to be implanted in the pelvic muscle, the pelvic muscle being adjacent to the urethral sphincter muscle.

103. (New) A device for inhibiting involuntary urine flow, comprising:

at least one electrode, which is adapted to be implanted in a pelvic muscle of a patient;

a sensor, which is adapted to perform a strain measurement of an abdomen or a urinary bladder of the patient, and to generate a signal responsive thereto; and

a control unit, which is adapted to receive the signal, analyze the signal to determine a level of abdominal stress of the patient, and, responsive thereto, apply an electrical waveform to the electrode which stimulates the muscle to contract so as to inhibit involuntary urine flow through the patient's urethra due to the stress.

104. (New) A device according to claim 103, wherein the control unit is adapted to apply the electrical waveform responsive to electromyographic signals received from the at least one electrode.

105. (New) A device according to claim 103, wherein the control unit comprises a processor, which is adapted to analyze the signals so as to determine when an involuntary urine flow is likely, whereupon the waveform is applied.

106. (New) A device according to claim 105, wherein the processor is programmable to vary one or more parameters associated with the application of the waveform.

107. (New) A device according to claim 103, wherein the control unit is adapted to be implanted in the body of the patient.

108. (New) A device according to claim 103, wherein the at least one electrode is adapted to be implanted in the levator ani muscle.

109. (New) A device according to claim 103, wherein the at least one electrode is adapted to be implanted in the urethral sphincter muscle.

110. (New) A device according to claim 103, wherein the at least one electrode is adapted to be implanted in the pelvic muscle, the pelvic muscle being adjacent to the urethral sphincter muscle.

111. (New) A device for inhibiting involuntary urine flow, comprising:

at least one electrode, which is adapted to be placed in electrical contact with a pelvic muscle of a patient; and

a control unit, which is adapted to receive electromyogram signals from the electrode and, responsive to a rate of change of the signals indicative of a possible involuntary urine flow, to apply an electrical waveform to the electrode which stimulates the muscle to contract, so as to inhibit the involuntary urine flow.

112. (New) A method for inhibiting involuntary urine flow of a patient, comprising:

implanting an electrode in a pelvic muscle of the patient;

receiving a pressure-measurement signal indicative of abdominal stress; and

responsive to the signal, applying an electrical waveform to the electrode, which stimulates the muscle to contract so as to inhibit involuntary urine flow.

113. (New) A method according to 112, wherein implanting the electrode in the pelvic muscle comprises implanting the electrode in the levator ani muscle.

114. (New) A method according to claim 112, wherein implanting the electrode in the pelvic muscle comprises implanting the electrode in the urethral sphincter muscle.

115. (New) A method according to claim 112, wherein implanting the electrode comprises implanting the electrode in proximity to the urethral sphincter muscle.

116. (New) A method according to claim 112, wherein applying the waveform comprises applying the waveform responsive to an electromyographic signal.

117. (New) A method for inhibiting involuntary urine flow of a patient, comprising:

implanting an electrode in a pelvic muscle of the patient;

receiving a strain-measurement signal indicative of abdominal stress; and

responsive to the signal, applying an electrical waveform to the electrode, which stimulates the muscle to contract so as to inhibit involuntary urine flow.

118. (New) A method according to 117, wherein implanting the electrode in the pelvic muscle comprises implanting the electrode in the levator ani muscle.

119. (New) A method according to claim 117, wherein implanting the electrode in the pelvic muscle comprises implanting the electrode in the urethral sphincter muscle.

120. (New) A method according to claim 117, wherein implanting the electrode comprises implanting the electrode in proximity to the urethral sphincter muscle.

121. (New) A method according to claim 117, wherein applying the waveform comprises applying the waveform responsive to an electromyographic signal.

122. (New) A method for inhibiting involuntary urine flow, comprising:

placing an electrode in electrical contact with a pelvic muscle of a patient;

receiving electromyogram signals from the electrode indicative of abdominal stress in the patient;

determining a rate of change of the signals; and

responsive to the rate of change, applying an electrical waveform to the electrode which stimulates the muscle to contract, so as to inhibit an involuntary urine flow.

123. (New) A method according to claim 122, wherein applying the waveform comprises applying a waveform when the rate of change is above a threshold rate, and comprising withholding the waveform when the rate of change is below the threshold rate so as to allow voluntary voiding.--

REMARKS

Claims 3, 5-12, 15-24, 31-40, 42-57, 62, 63, and 65-89 have been canceled, as they have been allowed in the parent application. Claims 92-123 have been added. No new matter has been introduced.

New claims 92 and 103 both correspond to claim 1 in the parent application, differing substantially only in that claim 92 now recites "a sensor, which is adapted to sense a change in pressure of an abdomen or a urinary bladder of the patient...," and in that claim 103 now recites "a sensor, which is adapted to perform a strain measurement of an abdomen or a urinary bladder of the patient..." These new claims are supported by the specification of the present patent application in a number of locations, for example in the second paragraph of Section G ("Utilization of other sensors"), starting at page 30, line 3, of the Detailed Description of Preferred Embodiments:

> "In addition to or instead of the electromyographic signals received from electrode 29, CPU 52 preferably receives additional signals from other physiological sensors, such as ultrasound transducer 44 (shown in Fig. 2), a pressure sensor 76 and/or an acceleration sensor 78, or other types of strain and motion measurement devices, as are known in the art. Pressure sensor 76 is preferably implanted on or in bladder 36, so as to detect increases in abdominal or intravesical pressure that may lead to involuntary urine loss."

Correspondingly, new method claims 112 and 117 are parallel to method claim 58, and now respectively recite the limitations of "receiving a pressure-measurement signal..." and "receiving a strain-measurement signal..." The support for these new claims is the same as the support for new claims 92 and 103.

Device claim 1 and the generally-parallel method claim 58 were rejected in the parent application under 35 USC 102(b) as being anticipated by US Patent 3,628,538 to Vincent et al. The Vincent patent is entitled (and describes throughout the specification thereof) "Apparatus for stimulating muscles controlled by the same muscles." Fundamental to the teaching of the Vincent patent is the idea of stimulating a muscle based on electrical changes in that muscle, in order to affect the contractions of that muscle. See, for example, Fig. 1 of that patent and the description thereof. In the text of the '538 patent, at column 1, lines 33-38, it is noted: "According to the present invention there is provided apparatus for controlling muscles in living animals, including man, comprising sensing means for sensing an electromyographic signal in a muscle, and stimulation means for automatically stimulating the same muscle in accordance with the characteristic of the signal sensed."

New claims 92, 103, 112, and 117, by contrast to the Vincent patent, claim apparatus and methods for sensing the mechanics of a stress-incontinence inducing event, such as a pressure change or tissue-strain change which occurs during coughing or heavy lifting. Whereas the Vincent patent is generally directed to detecting electrical physiological activity, namely the contractions of muscles trying to prevent incontinence, apparatus and methods described in new claims 92, 103, 112, and 117 do not necessarily require any voluntary or involuntary muscular activity by the patient in order to function, but, instead, act responsive to the cause of the stress incontinence, which is a mechanical phenomenon.

Therefore, 92, 103, 112, and 117, are of narrower scope than claims 1 and 58, do not read on the Vincent patent, and stand in condition for allowance, as per the agreement reached during the March 19, 2001, interview with respect to claims 1 and 58 in the parent application.

New claims 93-102 correspond directly to, and draw their support from, claims 2, 4, 13, 14, and 25-30 of the parent application, respectively. Similarly, claims 104-110 correspond directly to, and draw their support from, claims 2, 4, 13, 25, and 28-30 of the parent application, respectively. New claims 113-116 correspond directly to, and draw their support from, claims 59-61 and 64 of the parent application, respectively. Similarly, new claims 118-121 correspond directly to, and draw their support from, claims 59-61 and 64 of the parent application, respectively. It is respectfully submitted that since new claims 93-102 are of narrower scope than new claim 92, since new claims 104-110 are of narrower scope than new claim 103, since

new claims 113-116 are of narrower scope than new claim 112, and since new claims 118-121 are of narrower scope than new claim 117, each of claims 93-102, 104-110, 113-116, and 118-121 recite patentable subject material and are in condition for allowance.

New claims 111 and 122 are identical to claims 41 and 90 in the parent application, respectively. Claims 41 and 90 were rejected by the Examiner under 35 USC 102(b), as anticipated by the '538 patent. The teaching of the Vincent patent involves sensing the amplitude of an EMG signal, and applying stimulation responsive thereto. For example, at column 1, lines 39-40, of the '538 patent, it is stated: "Preferably, the means for sensing the signal includes means for monitoring the amplitude of the E.M.G. signal." Moreover, at column 2, lines 34-37, it is stated, "Smoothing is necessary so that the monostable circuit is insensitive to random spikes which sometimes appear in the E.M.G., but is triggered only by a persistent increase in the amplitude of the E.M.G" (emphasis added). A reason for the use of EMG amplitude analysis in the '538 patent is provided in the text itself, at column 2, lines 5-12:

> "During E.M.G. investigations of the muscles of the pelvic floor, in incontinent patients, it has been observed that there is a large increase in E.M.G. amplitude when the patient feels urgency, and is unable to prevent urination, as well as during coughing or under similar conditions of strain. It is at these times that external muscle stimulation is effective, and this increase in E.M.G. signal activity may be used as the control signal to initiate stimulation" (emphasis added).

Thus claims 111 and 122 are patentable over the '538 patent, as they recite apparatus and a method for determining a rate of change of EMG signals -- an analysis mode not suggested by the '538 patent. Moreover, new claim 123 is patentable as it is dependent on claim 122 and identical to claim 91 of the parent application.

Claims 13, 14, 25-27, 29, 30, 60, and 61 were rejected in the parent application under 35 USC 103(a), as being unpatentable over the '538 patent, further in view of US Patent 5,807,397 to Barreras. New claims 95-99, 101, 102, 114, and 115 correspond to claims 13, 14, 25-27, 29, 30, 60, and 61 in the parent application, respectively. Because these new claims are directly or indirectly dependent on independent claims which are now believed to be allowable, it is respectfully requested that these dependent claims be allowed, as well. Similarly, new claims

106, 107, 109, and 110, corresponding directly to claims 13, 25, 29, and 30, respectively, are believed to be patentable.

As all of the claims in the present application are in order for allowance, a notice of allowance is respectfully requested.

Respectfully submitted,

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